DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

October 8, 2014

Siemens Medical Solutions USA, Inc.
% Cordell L. Fields, Esq.
Regulatory Affairs Technical Specialist
51 Valley Stream Parkway, Mail Code D02
MALVERN PA 19355

Re: K142515
Trade/Device Name: MAGNETOM Combi Suite Neurosurgery for the MAGNETOM Systems Aera and Skyra
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: September 5, 2014
Received: September 8, 2014

Dear Mr. Fields:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142515

Device Name
"MAGNETOM Combi Suite Neurosurgery" for the MAGNETOM systems Aera and Skyra

Indications for Use *(Describe)*
Your MAGNETOM MR system [Aera/Skyra] is indicated for use as a magnetic resonance diagnostic device (MRDD) that produces transverse, sagittal, coronal and oblique cross sectional images, spectroscopic images and/or spectra, and that displays the internal structure and/or function of the head, body, or extremities. Other physical parameters derived from the images and/or spectra may also be produced. Depending on the region of interest, contrast agents may be used. These images and/or spectra and the physical parameters derived from the images and/or spectra when interpreted by a trained physician yield information that may assist in diagnosis.

Your MAGNETOM MR system [Aera/Skyra] may also be used for imaging during interventional procedures when performed with MR compatible devices such as in-room displays and MR Safe biopsy needles.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Food and Drug Administration
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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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Section 5 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of Safe Medical Device Act 1990 and 21 CFR § 807.92.

I General Information

Establishment

Siemens Medical Solutions USA, Inc.
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Mail Code D02
Malvern, PA 19355, USA
Registration Number: 2240869

Manufacturer

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Registration Number: 3002808157

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Contact Person

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Classification and Device Name

Trade name:	MAGNETOM Combi Suite Neurosurgery for the MAGNETOM systems Aera and Skyra.
Classification Name:	Regulation Description: - Magnetic Resonance Diagnostic Device (MRDD)
Classification Panel:	Radiology
Regulation number:	21 CFR § 892.1000

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Device Class:	II
Product Code:	LNH

II Safety and Effectiveness Information Supporting Substantial Equivalence

Device Description
MAGNETOM Combi Suite Neurosurgery is the marketing name for an optional package for the MAGNETOM systems Aera and Skyra that includes the modified Combi Dockable Table for use with standalone OR tables (Operation Room) in a clinical workflow. The market name, MAGNETOM Combi Suite Neurosurgery, refers to a sales bundle of single items that have been combined to build up a patient transfer workflow. MAGNETOM Combi Suite Neurosurgery enables the user to move a patient via the Combi Dockable Table from the OR table to the MR and vice versa in order to acquire intraoperative images.

The intended use of the MAGNETOM Aera, MAGNETOM Skyra, and the supported OR-Tables remains unchanged.

The MAGNETOM Combi Suite Neurosurgery will only be available for MAGNETOM systems Aera and Skyra and will be available as an option to newly manufactured scanners; existing scanners can be upgraded with this sales bundle. The sales bundles include new hardware for the MAGNETOM systems Aera and Skyra.

Summary of new features for MAGNETOM Combi Suite Neurosurgery:

Software
No software changes have been made with respect to the predicate device MAGNETOM Artis Combi Suite with K140253 cleared on March 20, 2014.

Hardware
Maquet Package
- Combi Dockable Table
- Interface Box
- NORAS[2] head holder

[2] The NORAS head holder is a medical device in its own right and was cleared under K133506 on August 6, 2014 and is not subject to this 510(k) submission

Trumpf Package (TruSystem 7500)

- Combi Dockable Table
- Interface Box
- Transfer Board
- Support cushion for Transfer Board
- NORAS^2 head holder
- Floor dock

Substantial Equivalence

The sales bundle MAGNETOM Combi Suite Neurosurgery for the MAGNETOM systems Aera and Skyra is substantially equivalent to the following current legally marketed device (**Table 1**):

Table 1: Predicate device for MAGNETOM Combi Suite Neurosurgery for the MAGNETOM systems Aera and Skyra

Predicate Device Name	FDA Clearance Number / Date	Manufacturer	Manufacturer, Product Code	Claim Substantial Equivalence to
MAGNETOM Artis Combi Suite for MAGNETOM systems Aera and Skyra	K140253, cleared March 20, 2014	Siemens AG	LNH	MAGNETOM Artis Combi Suite for MAGNETOM systems Aera and Skyra

This predicate has not been subject to any recalls.

Safety and Effectiveness

The device labeling contains instructions for use and any necessary cautions and warnings to provide for safe and effective use of the device.

Risk Management is ensured via a Risk Analysis in compliance with ISO 14971:2007 to identify and provide mitigation to potential hazards beginning early in the design cycle and continuing throughout the development of the product. Siemens Medical Solutions USA, Inc. and Siemens AG adhere to recognized and established industry standards, such as the IEC 60601-1 series, to minimize electrical and mechanical hazards.
The MAGNETOM systems Aera and Skyra with sales bundle MAGNETOM Combi Suite Neurosurgery conform to the applicable FDA recognized and international IEC, ISO and NEMA standards with regards to performance and safety as recommended by the respective MR FDA Guidance Document.

Indications for Use

The MAGNETOM MR [Aera/Skyra] system is indicated for use as a magnetic resonance diagnostic device (MRDD) that produces transverse, sagittal, coronal and oblique cross sectional images, spectroscopic images and/or spectra, and that displays the internal structure and/or function of the head, body, or extremities.
Other physical parameters derived from the images and/or spectra may also be produced. Depending on the region of interest, contrast agents may be used. These images and/or spectra and the physical parameters derived from the images and/or spectra when interpreted by a trained physician yield information that may assist in diagnosis.

The MAGNETOM MR system [Aera/Skyra] may also be used for imaging during interventional procedures when performed with MR compatible devices such as in-room displays and MR-safe biopsy needles.

Comparison of Technological Characteristics with the Predicate Device & Conclusion as to Substantial Equivalence

MAGNETOM Aera/Skyra with software *syngo* MR D13A as well as MAGNETOM Skyra with software *syngo* MR D13C combined with MAGNETOM Combi Suite Neurosurgery has the same intended use and the same technical characteristics as the predicate device (Table 1: Predicate device for MAGNETOM Combi Suite Neurosurgery for the MAGNETOM systems Aera and Skyra with respect to the magnetic resonance features and functionalities. The differences between the subject device and the predicate device, which include the aforementioned hardware, provide the MAGNETOM systems Aera and Skyra with additional capabilities by allowing the user to transfer a patient via the Combi Dockable Table from the OR table to the MR and vice versa in order to acquire intraoperative images.

There are no new issues of safety or effectiveness introduced with the MAGNETOM Combi Suite Neurosurgery. The basic functionality of MAGNETOM Combi Suite Neurosurgery remains the same to the predicate device (Table 1: Predicate device for MAGNETOM Combi Suite Neurosurgery for the MAGNETOM systems Aera and Skyra). However with this package, the MAGNETOM CombiSuite can now also be used within a Neurosurgery workflow / environment.

Therefore, Siemens believes that the subject devices, MAGNETOM Combi Suite Neurosurgery, are substantially equivalent to the predicate device, MAGNETOM Artis Combi Suite (Table 1).

III Performance Data

The following performance data is being provided in support of the substantial equivalence:

Biocompatibility Testing
The biocompatibility evaluation for MAGNETOM Combi Suite Neurosurgery was conducted in accordance with EN ISO 10993-1. The testing included the following tests:

- Cytotoxicity
- Skin Irritation
- Sensitization

Electrical safety and electromagnetic compatibility (EMC)
The MAGNETOM Combi Suite Neurosurgery does not contain active electrical circuits that require electromagnetic compatibility testing when not connected to the MR System.

In addition, within particular standard IEC 60601-2-33, chapter 202.6.101 the components of the MR system located inside the controlled area, are excluded from the requirements given in IEC60601-1-2: 2007, thus the Combi Dockable Table, even when energized via the MR System, does not need to be tested for electromagnetic compatibility.
For electrical safety the system complies to the IEC 60601-1.

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA´s Guidance for Industry and Staff "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices". The software for this device was considered as a "moderate" level of concern, since a failure or latent design flaw could directly result in minor injury to the patient or operator.

Bench and Acoustic Testing

- MR Imaging
- Spectroscopy
- Safety
  - Static Magnetic Field Strength
  - Acoustic noise level
  - dB/dt
  - RF Heating

IV Conclusions

The submitted data support the safety of the device. The hardware and software verification and validation demonstrate that the MAGNETOM CombiSuite Neurosurgery device performs as specified.